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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/822,670	04/13/2004	Arthur Earl Colvin JR.	2232-195	2881

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EXAMINER	
GROSS, CHRISTOPHER M	
ART UNIT	PAPER NUMBER
1639	

SHORTENED STATUTORY PERIOD OF RESPONSE	NOTIFICATION DATE	DELIVERY MODE
3 MONTHS	01/17/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Notice of this Office communication was sent electronically on the above-indicated "Notification Date" and has a shortened statutory period for reply of 3 MONTHS from 01/17/2007.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PTO-PAT-Email@rfem.com

Office Action Summary	Application No.	Applicant(s)	
	10/822,670	COLVIN ET AL.	
	Examiner	Art Unit	
	Christopher M. Gross	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 December 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-40* is/are pending in the application.

4a) Of the above claim(s) *22-35* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-21 and 36-40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/1/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Responsive to communications entered 12/13/2006. Claims 1-40 are pending. Claims 22-35 are withdrawn. Claims 1-21 and 36-40 are examined herein

Election/Restrictions

Applicant's 12/13/06 election without traverse of group I (claims 1-21 and 36-40) and the species: from claim 9 (solvent) hydroxyethyl methacrylate; from claim 12 (hydrophilic monomer) 2-hydroxyethyl methacrylate; from claim 19 (crosslinker) ethylene glycol dimethylacrylate; from claim 34 (analyte) glucose in the reply filed on 12/13/2006 is acknowledged.

Claims 22-35 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Priority

This application has a filing date of 4/13/2004. Applicant makes no claim for the benefit of any prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 8 and 10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "substantial" in claim 8 is a relative term which renders the claim indefinite. The term "substantial" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-12,14,17-19,36-40 are rejected under 35 U.S.C. 102(b) as being anticipated by **Singaram et al** (US Patent Application 2002/0106810) and evidenced by Kwok et al (2002 Polymer 45:4017-4027).

The claimed invention is drawn to a method for non-covalently attaching a macromolecular indicator to a support comprising:

(a) providing a support surface which comprises at least one polymer;

(b) changing the integrity of the polymer to provide loosened polymer chains that form at least one interlacing area;

(c) providing at least one macromolecular indicator or monomers thereof;

(d) causing the macromolecular indicator to interlace with said at least one interlacing area, or causing the sequential polymerization of said monomers to form polymerization products which interlace with said at least one interlacing area; and

(e) causing the loosened polymer chains to tighten to produce surface immobilized indicator molecules.

Claims 2-12,14,17-19,36-40 represent variations thereof.

Singaram et al teach, throughout the document and especially the abstract an optical sensing polyhydroxyl substituted polymer.

Specifically, Singaram et al teach in paragraph 0169 sensing copolymer molecules are immobilized on insoluble polymer matrix, reading on claim 1(a), 36(a). Singaram et al teach in paragraph 0055 the use of a interpenetrating (interlacing) copolymer which is water or organic solvent swellable (loosened) comprising copolymerizable sensor dyes (macromolecular indicators), therein reading on claim 1(b-d), 36(b-d).

Example polymers according to Singaram et al in paragraph 0172, include hydroxyethly methacrylate (HEMA) hydrogels which has different swelling properties in water versus organic solvents. Example organic solvents according to Singaram in paragraph 0151 include ethanol. Kwok exhibit in figure 4, the swelling of hydroxymethacylate gels in ethanol versus water, thus the HEMA hydrogels prepared by Singaram et al would inherently tighten, in upon exchanging ethanol for water instance, therein reading on claims 1(e), 7, 8, 11 and 37.

Said sensing coploymer of Singaram et al read on the indicator molecule of claims 2, 38.

Singaram et al teach in paragrapn 0176, sequential polymerization, reading on claims 3, 39.

Singaram et al teach in paragrapn 0169, organic and biocompatible support materials, which reads on the hydrophobic or hydrophilic support surfaces of claims 4 and 40.

Singaram et al teach in figure 1 sulfonated pyrene-PEG sensors, which reads on the hydrophilic indicator of claims 5 and 10.

Said optical sensing polyhydroxyl substituted polymer of Singaram et al reads on the sensor of claim 6.

Singaram et al teach in paragraph 0231 the use of HEMA as a solvent *and* monomer, reading on claim 9 (elected species) claim 12 (elected species) as well as the hydrophilic monomer of claim 10.

According to paragraph 0031 of the instant specification, "reference molecules are, for example, fluorescent molecules that emit at wavelengths different from the respective indicator molecule and are not responsive to changes in analyte concentration, but responsive to other aspects of the system analyzed, such as excitation intensity and pH" Singaram et al teach in figure figure 4A and 2 the introduction of pyridinyl-type quenching moieties, which have a different emission spectra from said sulfonated pyrene-PEG sensors and are sensitve to pH, thereby reading on claim 14.

Singaram et al teach in paragraph 0172 and 0146 the use of crosslinkers, including ethylene glycol dimethacrylate, reading on claim 19 (elected species).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-12,14,17-19, 36-40 and 13,15-16, 20-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Singaram et al** (US Patent Application 2002/0106810) in view of **Daniloff et al** (US Patent Application 2002/0090734) with evidence provided by Kwok et al (2002 Polymer 45:4017-4027) and Colvin et al (US Patent application 2003/0013204 – IDS entry 4/1/2004)

Singaram et al is relied on as above.

Singaram et al do not teach an indicator molecule comprising bis-carboxylate bi-boronate-anthracene (claim 13)

Daniloff et al teach, throughout the document and especially figure 3, bis-carboxylate bi-boronate-anthracene as an indicator molecule for the detection of glucose.

It would have been *prima facie* obvious for one of ordinary skill in the art, at the time the claimed invention was made to utilize the bis-carboxylate bi-boronate-anthracene of Daniloff et al to as part of the optical sensing polyhydroxyl substituted polymer of Singaram et al.

One of ordinary skill in the art would have been motivated to use the bis-carboxylate bi-boronate-anthracene of Daniloff et al to as part of the optical sensing polyhydroxyl substituted polymer of Singaram et al because bis-carboxylate bi-boronate-anthracene based sensors do not interact with other groups containing hydroxyl groups, therein making a more *selective* glucose sensor, as noted by Daniloff et al in paragraph 0009.

Colvin et al exhibit in paragraph 0055 that certain macromolecules exhibit a "excimer" effect such that when their pi electron orbital overlap, a characteristic downfield emmission occurs. According to to Colvin et al in paragraph 0056, example species exhibiting said eximer effect include pyrene (e.g sulfonated pyrene-PEG sensors of Singaram et al) and antracene (e.g. bis-carboxylate bi-boronate-anthracene of Daniloff et al) . Therefore, absent evidence to the contrary, a optical sensing polyhydroxyl substituted polymer of Singaram et al comprising a bis-carboxylate bi-

boronate-anthracene of Daniloff et al would contain at least some excimer regions, as set forth in claim 15 and 16.

Furthermore, free radical copolymerization represents a random process, absent evidence to the contrary, the sulfonated pyrene-acrylamide sensors shown in figure 1B and used in example 14 of Singaram et al would be expected to crosslink to one another to some extent, such as set forth in claims 20 and 21.

According to In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990): "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not."

One of ordinary skill could use the bis-carboxylate bi-boronate-anthracene of Daniloff et al to as part of the optical sensing polyhydroxyl substituted polymer of Singaram et al with a reasonable expectation of success since Daniloff et al has applied a bis-carboxylate bi-boronate-anthracene to a glucose sensor, therefore it is not unreasonable to add bis-carboxylate bi-boronate-anthracene to the optical sensing polyhydroxyl substituted polymer of Singaram et al because a bis-carboxylate bi-boronate-anthracene glucose sensor lies well within the scope of optical sensing polyhydroxyl substituted polymers.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher M. Gross whose telephone number is (571)272-4446. The examiner can normally be reached on M-F 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, J. Douglas Schultz can be reached on 571 272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Christopher M Gross
Examiner
Art Unit 1639

cg

JON EPPERSON
PRIMARY EXAMINER